

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Scott Manzo

EXAMINER: Lian Huang

SERIAL NO.: 10/516,437

GROUP ART UNIT: 3731

FILED: November 30, 2004

CONFIRMATION NO.: 2942

**FOR: METHOD AND APPARATUS FOR ANASTOMOSIS INCLUDING ANNULAR
JOINING MEMBER**

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT "A"

Sir:

In response to the Final Office Action mailed December 10, 2008, please amend this application as follows:

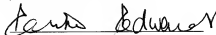
Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: May 5, 2009


Erika Edwards

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) An apparatus for performing a surgical anastomosis, comprising:
a tubular sleeve defining an axial lumen therethrough;
a positioning tube defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve;
an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube; and
an anchoring assembly including:
a flange member having a head portion and an expandable annular body integrally coupled to the head portion, the annular body defining a passage, the passage extending through the head portion and the annular body; and
a locking member configured and dimensioned to be received in the passage of the annular body, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member ~~within~~ inside the passage of the annular body.

2. (Original) The apparatus according to claim 1, wherein the expandable tip of the expansion assembly is a balloon.

3. (Original) The apparatus according to claim 1, wherein the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is expandable along the pair of longitudinal slots.

4. (Original) The apparatus according to claim 3, wherein the annular body of the anchoring assembly includes a plurality of protuberances formed on an outer surface thereof.

5. (Original) The apparatus according to claim 3, wherein the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded.

6. (Original) The apparatus according to claim 5, wherein the head portion of the flange member has a radius which is larger than the first radius of the annular body.

7. (Original) The apparatus according to claim 6, wherein the locking member comprises a cylindrical body having a distal end portion, wherein the cylindrical body has a radius which is larger than the first radius of the annular body and wherein the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body.

8. (Original) The apparatus according to claim 3, wherein the longitudinal slots extend through a proximal terminal end of the annular body and terminate at a distance spaced from the head portion.

9. (Original) The apparatus according to claim 1, wherein the head portion includes a plurality of protuberances formed on a proximal surface thereof.

10. (Original) The apparatus according to claim 1, wherein the head portion includes a tapered distal surface.

11. (Original) The apparatus according to claim 1, wherein the annular body of the anchoring assembly comprises a plurality of longitudinal slots formed therein.

12. (Original) The apparatus according to claim 1, wherein the annular body of the anchoring assembly comprises at least one helical slot extending through the terminal end of the annular body.

13. (Original) The apparatus according to claim 1, wherein a proximal end of the locking member is configured and adapted to engage a distal end of the positioning tube.

14. (Original) The apparatus according to claim 1, wherein the head portion of the flange member has a radius which is larger than a radius of the lumen of the tubular sleeve.

15. (Original) The apparatus according to claim 1, wherein the head portion of the flange member has a radius which is smaller than an inner radius of the lumen of the tubular sleeve.

16. (Original) The apparatus according to claim 1, wherein the anchoring assembly is made from a bio-absorbable material.

17. (Previously Presented) A method for performing a surgical anastomosis, comprising the steps of:

providing an apparatus for performing an the surgical anastomosis, the apparatus comprising:

a tubular sleeve defining an axial lumen therethrough;

a positioning tube defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve;

an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube; and

an anchoring assembly including:

a flange member having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member arranged to be received in the passage of the flange member, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body;

passing the apparatus through a body lumen and through an opening in a body vessel such that the head portion of the flange member of the anchoring assembly is positioned within the body vessel;

advancing the expansion assembly through the positioning tube such that the expandable tip is within the body vessel;

expanding the expandable tip within the body vessel;

withdrawing the tubular body of the expansion assembly to press the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen;

advancing the positioning tube through the tubular body to drive and secure the discrete locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward against the inner surface of the body lumen.

18. (Original) The method according to claim 18, further comprising the step of retracting the expandable tip of the expansion assembly.

19. (Original) The method according to claim 18, further comprising the step of withdrawing the tubular body, the positioning tube and the expansion assembly from the body lumen.

20. (Original) The method according to claim 19, wherein the surgical anastomosis is a radical prostatectomy.

21. (Original) The method according to claim 20, wherein the radical prostatectomy includes the steps of removing the prostate gland from between the urethra and the bladder to define a urethral stump and a bladder neck.

22. (Currently Amended) An anchoring assembly for use in a surgical anastomosis procedure, comprising:

a flange member having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member discrete from the flange member, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within inside the passage of the annular body such that the locking member is secured within the passage of the annular body.

23. (Original) The anchoring assembly according to claim 22, wherein the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is expandable along the pair of longitudinal slots.

24. (Original) The anchoring assembly according to claim 23, wherein the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded.

25. (Original) The anchoring assembly according to claim 24, wherein the head portion of the flange member has a radius which is larger than the first radius of the annular body.

26. (Original) The anchoring assembly according to claim 25, wherein the locking member comprises a cylindrical body having a distal end portion, wherein the cylindrical body has a radius which is larger than the first radius of the annular body and wherein the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body.

27. (Original) The anchoring assembly according to claim 26, wherein the longitudinal slots extend through a proximal end of the annular body and terminate at a distance spaced from the head portion.

REMARKS

The present application has been reviewed in light of the Office Action dated December 10, 2008. Claims 1-27 are currently pending, of which claims 1 and 22 have been hereby amended. In view of the amendments above and the remarks to follow, reconsideration and allowance of this application are respectfully requested.

Claims 1-6, 8-15, 17-19 and 22-25 are rejected under 35 U.S.C. § 102(b) as by U.S. Patent No. 6,206,913 to Yencho et al. (hereinafter Yencho). Applicant respectfully submits that each of independent claims 1, 17 and 22 is allowable over Yencho because Yencho fails to disclose or suggest each and every element of independent claims 1, 17 and 22. Accordingly, the rejection of independent claims 1, 17 and 22, under 35 U.S.C. § 102(b) is respectfully traversed.

Pursuant to 35 U.S.C. § 102, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Applicant respectfully submits that Yencho fails to disclose each and every element recited in independent claim 1, as required by 35 U.S.C. § 102.

According to the Office Action, Yencho discloses “an apparatus for performing a surgical anastomosis, comprising: a tubular sleeve (134) defining an axial lumen therethrough; a positioning tube (136) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve (figure 28A); an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial

lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (148, column 13, lines 14-16, where it is implied that 148 cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and an anchoring-assembly including: a flange member (122) having a head portion and an expandable annular body integrally coupled to the head portion, the annular body defining a passage (figure 29), the passage extending through the head portion and the annular body; and a locking member (111) defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where “within” is taken to mean “inside the limits of”).

In fact, Yencho discloses a system for attaching a graft vessel 125 to a target blood vessel 127 by applying a large vessel stent 110 (see FIG. 12 reproduced below). The system includes an applicator 131 (see FIG. 23) for applying the stent 110, which includes an outer tubular member 134 and an inner tubular member 136. The inner tubular member 136 may be rotated within the outer tubular member 134 to deploy the stent 110. (see, e.g., Col. 10, lines 26 through 36; Col. 12, line 66 through Col. 13, line 18).

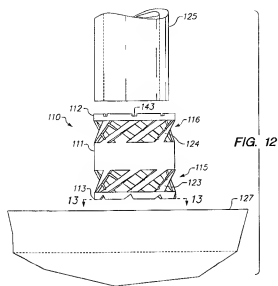


FIG. 12

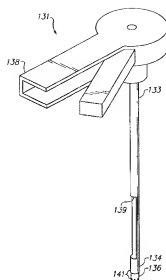
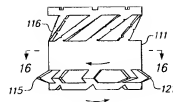
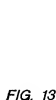
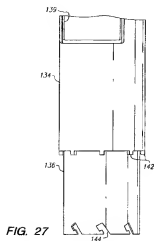
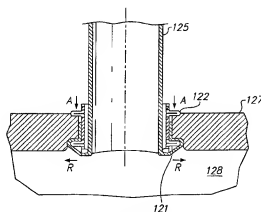


FIG. 23

In particular, inner and outer tubular members 136, 134 include connecting members 141 thereon to engage the stent 110. The connecting members 141 may take the form of tabs 142 and angular slits 144 as best seen in FIG. 27 below. The tabs 142 engage slits 143 on a proximal end of the stent 110 and the angular slits 144 engage tabs 145 (FIG 13) that protrude into the stent 110 (see col 12, lines 6-19). As depicted in FIG. 15, relative rotation of the tabs 145 and the slits 143 expand a distal deformable section 115 of the stent 110 to form a distal end flange 121. As depicted below, the distal end flange 121 "is configured to apply a force radial to the cylindrical body 111 longitudinal axis against the target body vessel." (Column 10, lines 28-30)



Similarly a proximal end flange 122 may be formed from proximal deformable section 116 by further rotating the inner and outer members 136, 134 (see col. 13, lines 19-40). Once the proximal end flange 122 is formed, the inner and outer members 136, 134 of applicator 131 may be withdrawn, and end flanges 121 and 122 remain in place to attach graft vessel 125 to the target vessel 127 as depicted in FIG. 20 below.



As indicated above, Yencho discloses a single-component stent 110 that is radially expanded by relative rotation of inner and outer tubular members of an applicator 131, which is subsequently withdrawn. The stent 110 is not radially expanded by a separate locking member that is received inside an annular body of a flange member, as described in Applicant's specification and required by

claim 1. Furthermore, Applicant asserts that the cylindrical body 111 of Yencho cannot be interpreted to recite a locking member as defined by Applicant's specification and claims. In fact, the only two references in Yencho's specification describing the cylindrical body 11 include that the "large vessel stent 110 comprises a substantially cylindrical body 11 having an open proximal end 112, open distal end 113, a lumen 114 extending therein configured to receive the end of the graft vessel 125 (column 10, lines, 4-7)," and that the "distal end flange 121, [is] configured to apply a force radial to the cylindrical body 111 longitudinal axis against the target vessel and thereby connect the stent to the target vessel (column 10, lines 28-30)." The cylindrical body 111 of Yencho is integral with the distal and proximal flange members and cannot be inserted within or inside the flange member 112 as the Office Action suggests.

Nowhere does Yencho disclose each and every limitation of independent claim 1 including an apparatus for performing a surgical anastomosis including, "a tubular sleeve defining an axial lumen therethrough; a positioning tube defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve; an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube; and an anchoring assembly including: a flange member having a head portion and an expandable annular body integrally coupled to the head portion, the annular body defining a passage, the passage extending through the head portion and the annular body; and a locking member configured and dimensioned to be received in the passage of the annular body, the locking member defining a lumen therethrough, the locking member being

configured and adapted to radially deflect the expandable annular body upon insertion of the locking member inside the passage of the annular body.”

The present application describes an embodiment in which, as depicted in FIG. 1 below, apparatus 100 includes a flange member 142. The flange member has an annular body 160 with a central opening 162 extending therethrough. Apparatus 100 also includes a locking member 144 that is discrete from the flange member 142. As depicted in FIG. 3C below, the locking member 144 is secured within the central opening 162 of the annular body 160 when the positioning tube 120 is withdrawn.

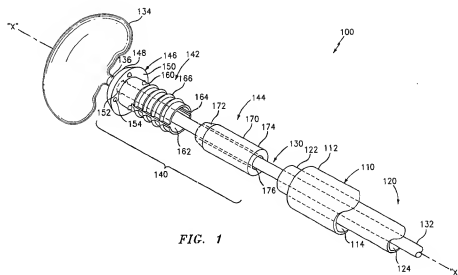


FIG. 1

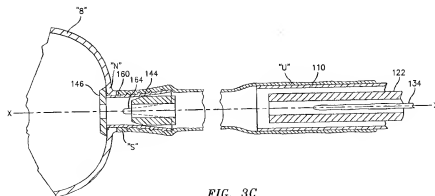


FIG. 3C

In view of the foregoing, Applicant respectfully submits that each and every feature of independent claim 1 is not taught or disclosed by Yencho. Yencho fails to teach or disclose an anchoring assembly having a flange member having a head portion and an expandable annular body integrally coupled to the head portion, the annular body defining a passage, the passage extending through the head portion and the annular body; and a locking member configured and dimensioned to be received in the passage of the annular body, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body.

Therefore, it is respectfully requested that the rejection of claim 1 be withdrawn.

As claims 2-6 and 8-15 depend directly or indirectly from claim 1 and contain all of the limitations of independent claim 1, Applicant respectfully submits that claims 2-6 and 8-15 are unanticipated by Yencho and are otherwise allowable.

With respect to claim 17, the Office Action states Yencho discloses *inter alia* a method for performing a surgical anastomosis, the apparatus comprising: a tubular sleeve (143) defining an axial lumen therethrough; a positioning tube (136) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve; an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (148, column 13, lines 14-16, where it is implied that 148 cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and an anchoring assembly including: a flange member (122)

having a head portion and an expandable annular 25 body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and a locking member (111) arranged to be received in the passage of the flange member (figure 29), the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where "within" is taken to mean "inside the limits of"); passing the apparatus through a body lumen and through an opening in a body vessel such that the head portion of the flange member of the anchoring assembly is positioned within the body vessel (figure 28E); advancing the expansion assembly through the positioning tube such that the expandable tip is within the body vessel; expanding the expandable tip within the body vessel (figures 28C and 28D); withdrawing the tubular body of the expansion assembly to press the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen; advancing the positioning tube through the tubular body to drive the locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward against the inner surface of the body lumen (figures 28A-H, column 11, lines 1-24).

Independent claim 17 recites a method for performing a surgical anastomosis including the step of, *inter alia*, "an anchoring assembly including a locking member arranged to be received in the passage of the flange member, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body; and advancing the positioning tube through the tubular body to drive and secure the discrete locking member of the anchoring assembly

into the annular body of the flange member and to deflect the annular body radially outward against the inner surface of the body lumen.” As discussed above, Yencho fails to teach or disclose at least a separate locking member that is received within a flange member as called for in independent claim 17. Applicant asserts that the cylindrical body 111 of Yencho is integral with the distal and proximal flange members and cannot be inserted within or inside the flange member 112. Furthermore, the cylindrical body 111 (of Yencho) cannot be interpreted to recite a locking member as defined by Applicant’s specification and claims.

Additionally, Applicant respectfully disagrees with the Office Action’s characterization of the term “within.” The words of a claim must be given their “plain meaning” unless such a meaning is inconsistent with the specification. During examination, The USPTO must give claims their broadest reasonable interpretation in light of the specification. “Plain meaning refers to the ordinary and customary meaning to a person of ordinary skill in the art.” See MPEP section 2111.01.

“The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.The ordinary and customary meaning of a term may be evidenced by a variety of sources,> including ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and the extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.’ <Phillips v. AWH Corp., *> 415

*F3d at 1314<, 75 USPQ2d **> at 1327."*

As detailed in applicant's specification and further detailed in the drawings (FIGS. 1-3B) "the more the locking member 144 is advances distally the more the annular body 60 deflects radially." (paragraph [0055]) When viewing the drawings and the Applicant's associated description in the specification, it is clear the locking member is discrete and advances distally to deflect the annular body 160 radially. Later, as stated in the applicant's specification "by driving locking member forward, the distal end 172 of the locking member 144 enters central opening 162 of annular body 160 (paragraph [0058]). Applicant asserts that the cylindrical body 111 of Yencho is integral with the distal and proximal flange members and cannot be inserted within or inside the flange member 112. Furthermore, the cylindrical body 111 (of Yencho) cannot be interpreted to recite a locking member as defined by Applicant's specification and claims. To interpret the cylindrical body 111 as the locking member 144 as suggested by the Office Action is contrary to both the plain meaning of the claim terms, as well as the teaching in the specification.

Accordingly, Applicant respectfully requests that rejection of claim 17 be withdrawn. As claims 18-19 depend, directly or indirectly, from claim 17 and contain all of the limitations of independent claim 17. Applicant respectfully submits that claims 18-19 are unanticipated by Yencho and otherwise allowable.

With respect to claim 22, the Office Action states Yencho discloses an anchoring assembly comprising: a flange member (122) having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and a locking member (111) discrete from the flange member (where

“discrete” is taken to mean “distinct”), the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where “within” is taken to mean inside the limits of”) such that the locking member is secured within the passage of the annular body (figure 20, where part 111 cannot extend or expand past part 122).

Independent claim 22 recites “a locking member discrete from the flange member, the locking member . . . being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body such that the locking member is secured inside the passage of the annular body.” As discussed above, Yencho discloses a stent 110 that may be radially expanded by applicator 131 that is subsequently withdrawn. Yencho fails to teach or disclose an expandable annular body that is expanded upon insertion of a discrete locking member that is secured within the annular body.

Furthermore, Applicant respectfully disagrees with the Office Action’s characterization of the term “discrete.” As cited above, the words of a claim must be given their “plain meaning” unless such a meaning is inconsistent with the specification. During examination, The USPTO must give claims their broadest reasonable interpretation in light of the specification. “Plain meaning refers to the ordinary and customary meaning to a person of ordinary skill in the art.” See MPEP section 2111.01.

As detailed in the Applicant’s specification and further detailed in the associated drawings, the locking member 144 is a separate component which interacts with the flange member (166). As previously mentioned, “the more the locking member 144 is advances distally the more the annular body 60 deflects radially.” (paragraph [0050]) When viewing the drawings

and the Applicant's associated description in the specification, it is clear the locking member is discrete and a separate component that the flange member 166. Later, as stated in the applicant's specification "by driving locking member forward, the distal end 172 of the locking member 144 enters central opening 162 of annular body 160." (paragraph [0058]) Conversely, Yencho discloses a cylindrical body 111 which is integral with the distal and proximal flange members and cannot be inserted within or inside the flange member 112. To interpret the Applicant's locking member 144 a single, shared component with the flange member 166, moreover, to interpret the cylindrical body 111 as the locking member 144, as suggested by the Office Action, is contrary to both the plain meaning of the claim terms, as well as the teaching in the specification.

Accordingly, Applicant respectfully requests that the rejection of claim 22 be withdrawn.

As claims 23-25 depend, directly or indirectly, from claim 22 and contain all of the limitations of independent claim 22, Applicant respectfully submits that claims 23-25 are also unanticipated by Yencho and otherwise allowable.

Claim 16 stands rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 6,629,988 to Weadock (hereinafter "Weadcock"). Applicant submits that claim 16 is allowable under 35 U.S.C. § 103(a) over Yencho in view of Weadock.

The Examiner relies on Weadock for the disclosure of an anchoring assembly made from a bio-absorbable material. Weadock relates generally to an anastomosis type staple. Applicant submits that Weadock fails to cure the deficiencies of Yencho, including that Weadock does not disclose the flange member and the locking member arrangement, as recited in independent claim 1.

Accordingly, in view of the foregoing, since Weadock fails to cure the deficiencies of

Yencho, Applicant submits that claim 16 is allowable under 35 U.S.C. § 103(a) over Yencho in view of Weadock.

Claims 7, and 26-27 stand rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 6,206,913 to Evard et al. (presumably, Examiner intended to refer to 6,616,675 to Evard et al.) (hereinafter "Evard"). Applicant submits that claims 7, and 26-27 are allowable under 35 U.S.C. § 103(a) and patentable as a whole.

The Examiner relies on Evard for the disclosure of a cylindrical body with a taper. Evard relates to various anastomotic connectors and apparatus for forming and/or maintaining connections between openings formed in anatomical structures. Evard fails to cure the deficiencies of Yencho including that Evard does not disclose the flange member and the locking member arrangement, the locking member being configured and adapted to radially deflect the expandable annular body, as recited in independent claims 1 and 22.

Accordingly, in view of the foregoing, since Evard fails to cure the deficiencies of Yencho, Applicant submits that claims 7, and 26-27 are allowable under 35 U.S.C. § 103(a) and patentable as a whole.

Claims 20-21 stand rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 5,591,179 to Edelstein (hereinafter "Edelstein").

Applicant submits that claims 20-21 are allowable under 35 U.S.C. § 103(a) over Yencho in view of Edelstein.

The Examiner relies on Edelstein for the disclosure of the teaching of a technique of


anastomosis in radical prostatectomy. Edelstein relates to a device for deploying a needle and suture to suture the urethral stump and bladder to one another. Edelstein fails to cure the deficiencies of Yencho including that Edelstein does not disclose "an anchoring assembly including a locking member arranged to be received in the passage of the flange member, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body; and advancing the positioning tube through the tubular body to drive and secure the discrete locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward against the inner surface of the body lumen," as recited in independent claim 17.

Accordingly, in view of the foregoing, since Edelstein fails to cure the deficiencies of Yencho, Applicant submits that claims 20-21 are allowable under 35 U.S.C. § 103(a) and claims 20-21 are patentable as a whole.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in this application, namely Claims 1-27, are in condition for allowance. Accordingly, early and favorable reconsideration of this application is respectfully requested. Should the Examiner feel that a telephone or personal interview may facilitate resolution of any remaining matters, he or she is respectfully requested to contact the Applicant at the number indicated below.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,



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